AUG 1 8 2000

K001773

ONI, Inc.

790 Turnpike Street
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North Andover, MA 01845

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2 Administrative Information

2.1 510(k) Summary

PREMARKET NOTIFICATION 510(k) Summary
(As Required by 21 CFR 807.92 (c))

Submitter Information

Contact:	Michael A. Douglas Manager of Quality Assurance and Compliance Ph. (978)683-8881 (x20) Fx (978)683-3211
Company:	ONI Incorporated 790 Turnpike Street Suite 100 North Andover, MA 01845

Device Information

Device Name:	ORTHONE
Common Name:	Orthopedic MR Scanner
Classification:	Magnetic Resonance Imaging System
Product Code:	LNH, Class II 21 CFR Section 892.1000

Predicate Devices:

The ORTHONE MRI system is substantially equivalent to the currently marketed Artoscan M and the 1.0 T Signa Horizon Cx systems with extremity coil.

Device Description:

The ORTHONE MRI system utilizes a superconducting magnet to acquire 2D single-slice and multi-slice and 3D volume images. A wide variety of pulse sequences is provided to the operator, including spin echo, fast spin echo, 2D and 3D gradient echo acquisitions. Imaging options such as inversion recovery, flow compensation and fat/water suppression are provided to suppress artifacts due to physiological motion and improve image quality. The system can be used as a stationary system.

Indications for Use:

The ORTHONE MRI system is indicated for use as a diagnostic imaging device to produce transverse , sagittal, coronal and oblique images of the internal structures of the extremities. The images produced by the ORTHONE MRI system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Predicate Comparison:

The ORTHONE MRI system is comparable to the Artoscan M with the main difference being the 1.0 T magnet, and RF electronics, which allow for increased S/N and quadrature RF coils.

The ORTHONE MRI system is comparable to the 1.0 T Signa Horizon Cx system with extremity coil. The main difference is the small size of the magnet due to its dedicated purpose design for imaging extremities.

Summary of Studies:

The ORTHONE MRI system was evaluated to applicable NEMA performance standards as well as IEC 60601, International medical equipment safety standard and IEC 60601-2-33, Particular requirements for safety of magnetic resonance equipment for medical diagnosis. The ORTHONE MRI system is comparable to the Artoscan M and the 1.0 T Signa Horizon Cx with extremity coil.

Conclusions:

It is the opinion of ONI Incorporated that the ORTHONE MRI system is substantially equivalent to both the Artoscan M and the 1.0 T Signa Horizon Cx system with extremity coil. The ORTHONE MRI system does not include any new indications for use or result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2000

Michael A. Douglas
Manager of Quality Assurance and Compliance
ONI, Incorporated
790 Turnpike Street, Suite 100
North Andover, MA 01845

Re: K001773
ORTHONE (Orthopedic MR Scanner)
Dated: June 9, 2000
Received: June 12, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Douglas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

2.2 FDA Indications for Use Form

Indications for Use

Center for Devices and Radiological Health

510(k) Number (if known): K 0 0 1773

Device Name: ORTHONE

Indications for Use:

The ORTHONE MRI system is intended for magnetic resonance imaging of the leg (excluding the thigh), knee, ankle, foot, elbow, forearm, wrist, and hand. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. If interpreted by a trained physician, these images can provide diagnostically useful information.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001773

Prescription use ✓